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## CASE REPORT

# Treatment of an osteoporotic vertebral compression fracture with the StaXx FX system resulting in intrathoracic wafers: a serious complication

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### Abstract

**Purpose** To report a serious complication of the StaXx FX system used to stabilize an osteoporotic vertebral fracture.

**Case report** A 76-year-old woman presented with a painful vertebral fracture. Treatment by means of a PEEK wafer kyphoplasty was complicated by malposition of the wafers. The patient recovered fully after removal of the wafers by means of a thoracotomy.

**Conclusions** New treatment modalities have their own pitfalls and possible complications, as demonstrated in this case report. Caution regarding implementation of new treatment modalities should be practiced.

**Keywords** Spine · Osteoporosis · Fracture · Kyphoplasty · StaXx FX

### Introduction

The impact of osteoporotic vertebral compression fractures (VCF) on mortality [1] and quality of life [2] is increasingly acknowledged. Despite successful conservative treatment of the majority of patients [3], 37% of patients referred for an X-ray of the thoracic or lumbar spine by their general practitioner still experience pain after six months [4]. Vertebroplasty (VP), originally developed for treatment of vertebral angiomas [5] and kyphoplasty (KP) are now commonly accepted treatment options for VCFs.

Potentially serious complications (cement leakage leading to pulmonary emboli or neurological deficit) of VP and KP have been reported [6–8]. An alternative KP procedure uses sequentially inserted 1-mm thick polyetheretherketone (PEEK) wafers for controlled and vertically oriented kyphosis correction (StaXx FX system, Spine Wave, Inc, Shelton, USA). The theoretical advantages over other VP and KP procedures are retained fracture reduction, less cement leakage and restoration of the load-bearing properties of the intervertebral disc [9].

Complications can occur with all surgical procedures, but especially when they are serious and occur while using a new device lacking clinical results publication is warranted. We present a case report of a PEEK wafer KP resulting in anterolateral perforation of the vertebral body, necessitating a thoracotomy.

### Case report

A 76-year-old, vital woman with a history of osteoporosis and a transient ischemic attack visited our outpatient clinic, with high back pain, interfering with daily activities. The pain occurred spontaneously 2 months earlier, and did not

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**Fig. 1** Thoracic spine X-rays showing the T7 fracture

improve with acetaminophen and activity modification. On physical examination (59 kg, 1.58 m), compression pain over the spinal column and painful palpation of the spinous processes T6 and T7 was noted. Thoracic spine X-rays revealed an impression deformity of T7, with 15% anterior height loss (Fig. 1), AO type A1.2. MRI showed oedema, sign of a recent/active fracture. Due to failure of conservative therapy, the fracture was stabilized using a PEEK wafer KP.

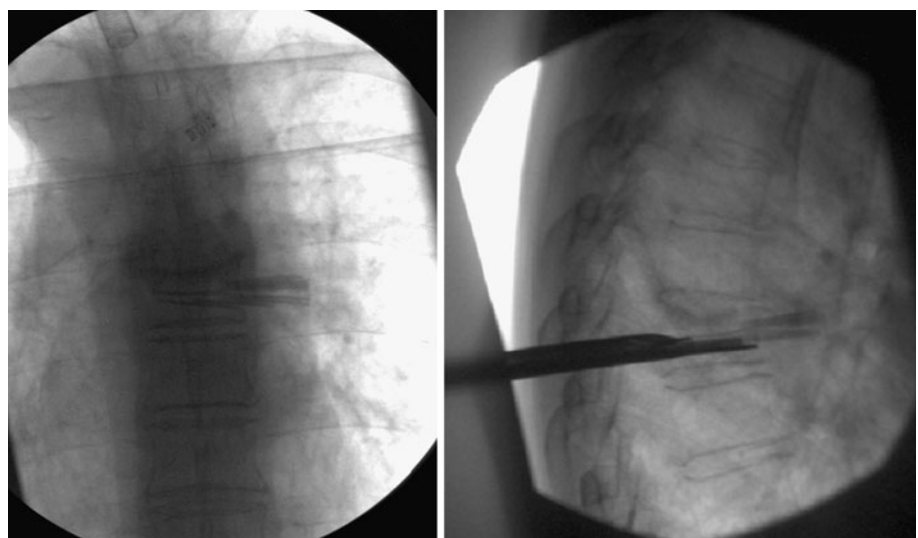
After general anaesthesia and antibiotic prophylaxis (1,000 mg cefamandole) and prone positioning, a K-wire

was inserted from a left extrapedicular entry position using fluoroscopy. After measuring the length, the sizer was inserted followed by gently tapping the wafer gun into the vertebra. The device penetrated the anterolateral cortex, and was withdrawn to the correct depth. During insertion of the first few wafers anterolateral protrusion was observed on fluoroscopy. Despite this observation, more wafers were introduced and these seemed to be positioned correctly. However, subsequent wafers again seemed to protrude (Fig. 2), therefore the procedure was terminated. Stabilization of the wafers by adding bone cement was omitted because of potential cement leakage into the thoracic cavity. The patient remained stable, and a direct postoperative X-ray revealed no pneumothorax, thus watchful waiting was performed after consulting a thoracic surgeon.

The thoracic spine X-ray performed the following day confirmed malposition of the wafers. The patient remained in good general condition, and was discharged from the hospital. The patient was prescribed acetaminophen with codeine 500/20 mg 4 times 2 daily and tramadol 50 mg 3 times 1 daily (VAS 4).

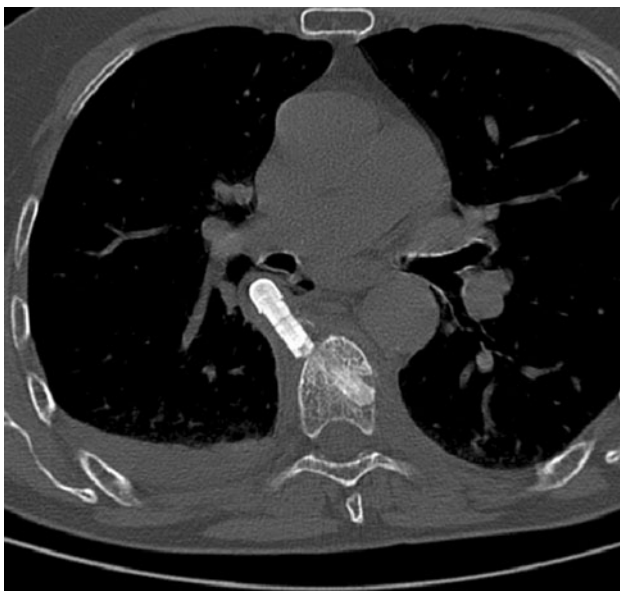
One week later she visited the emergency department with unbearable high back and right-sided thoracic pain (VAS 10), without dyspnoea. Tramadol had been replaced with Naproxen because of hallucinations. On physical examination, she was hemodynamically stable, without neurological deficit, but axial compression of the spinal column was painful. There were no signs of infection. Progressive displacement of one wafer was noted on the thoracic spine X-ray (Fig. 3). The anterior vertebral height loss had increased to 32%, probably due to the weakening of the vertebral body by the previous surgery. A CT-scan revealed protrusion of the wafers, in close proximity to the right pulmonary artery and stem bronchus, with fluid in the right pleural cavity (Fig. 4). After consultation with the

**Fig. 2** Intra-operative fluoroscopy of malpositioned wafers





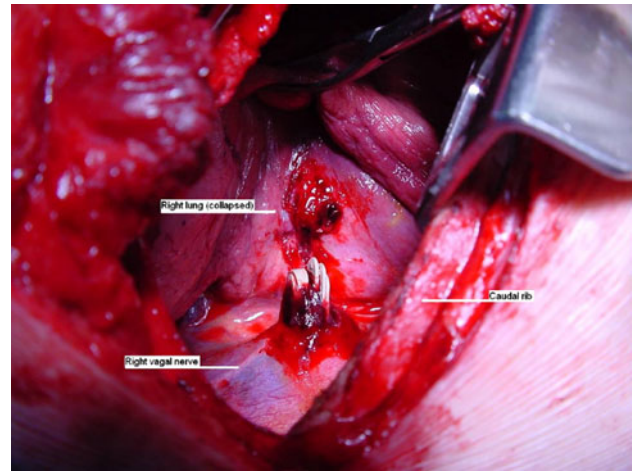
**Fig. 3** X-ray of the thoracic spine showing progressive malposition of one of the wafers



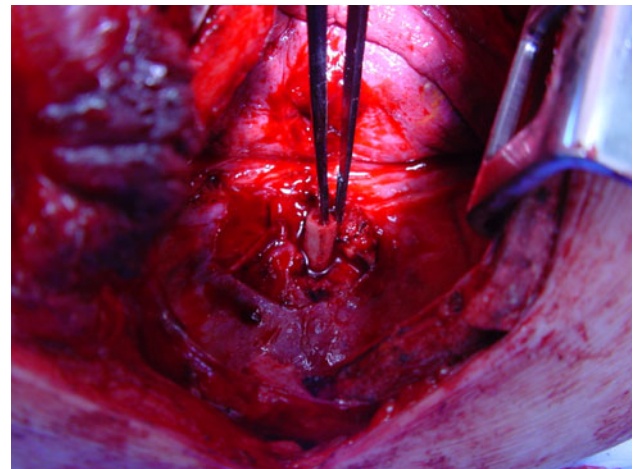
**Fig. 4** CT-scan transversal view showing the malpositioned wafers with close relation to the right pulmonary artery and right stem bronchus

thoracic surgeon, we decided to remove the wafers, and use an alternative method of stabilisation.

Following general anaesthesia and antibiotic prophylaxis (1,000 mg cefamandole) and left-sided positioning a right posterolateral thoracotomy was performed. By blocking ventilation the right lung collapsed. The wafers penetrated the parietal and visceral pleura (Fig. 5). The vagal nerve was



**Fig. 5** Intra-operative photo showing the protruding wafers



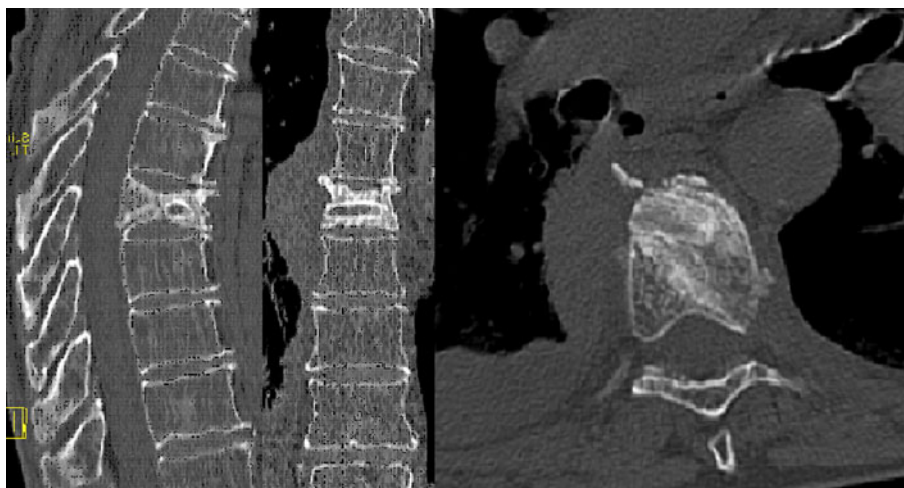
**Fig. 6** Intra-operative photo showing the resected piece of rib before insertion in the vertebral body

stretched around the wafers, but intact. After removal of the wafers, the residual cavity in the vertebral body was probed and deemed circumferentially intact. It was filled with a resected piece of the sixth rib (Fig. 6). An intrathoracic suction drain and a subpleural analgesic catheter were inserted. The right lung was inflated and the thoracotomy closed with thick double stranded sutures followed by routine wound closure.

Postoperatively she went to the ICU, and was transferred to the orthopaedic ward the next day after a thoracic X-ray revealed absent residual pneumothorax. Within 2 days the excruciating pain subsided, although analgesics were required for thoracotomy wound pain. X-rays and a CT-scan showed proper positioning of the rib-graft in the vertebra (Fig. 7). Three days postoperation, atrial fibrillation developed and was successfully treated with digoxin. She was discharged in good health after 19 days with a 3-point extension spinal orthosis for 6 weeks.



**Fig. 7** Postoperative CT-scan of the thoracic spine showing the position of the rib graft within the vertebral body



## Discussion

We present a serious complication of a PEEK wafer KP procedure in an osteoporotic VCF. Fortunately, the patient recovered extremely well. In addition to investigating characteristics of bone substitutes to decrease complications of VP and KP [10–13], alternatives and modifications of VP and KP are currently emerging. These include lordoplasty [14], vesselplasty [15], vertebral body stenting [16], mesh-allograft-stenting [17], among others [18], as well as the StaXx FX system. In experimentally created VCFs, partial endplate reduction and kyphosis correction could be achieved with the StaXx FX system, with intervertebral disk pressure corrected to 86% of normal [9]. In addition, in 26 VCFs treated with the device, a significant decrease in visual analogue scale (VAS) pain score was observed after 8 months of follow-up [19]. No clinical reports comparing these alternatives of VP and KP to regular VP or KP or conservative treatment are available. Surgical treatment of VCFs unresponsive to conservative therapy (with VP or KP) remains controversial [20–29]. In a subgroup of patients, VP appears to be superior to conservative treatment [30]. Unfortunately, at the moment it is not possible to identify these patients shortly after they sustain a VCF.

Regarding the complication described in this article, we think there are two possible explanations:

1. Perforation of the vertebral cortex with the wafer gun, creating a hole through which the wafers could protrude (faulty surgical technique). Perhaps at this moment switching to another method of stabilisation (for instance posterior instrumentation) would have been preferred. A more gradual increase in diameter of the wafer gun possibly lowers resistance during insertion, which might reduce occurrence of this complication.

2. A design flaw in the wafer gun allowing the wafers to progress beyond its anterior rim. Perhaps a higher anterior rim or different wafer shape would prevent this.

Incidence and prevalence of osteoporotic VCFs will increase. Heightened awareness of their impact on quality of life and mortality is changing our view of these fractures. Patients today are better informed and more assertive, in demanding (surgical) treatment. Nevertheless, we need to remain critical of new treatment modalities while their (long-term) results and complications are unknown. We feel it is important to describe complications occurring while using (new) surgical systems.

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**Conflict of interest** None of the authors has any potential conflict of interest.

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